



NRC NEWS

U.S. NUCLEAR REGULATORY COMMISSION

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NRC TO DISCUSS CONCERNS ABOUT RADIATION SAFETY PROGRAMS AT FDA FACILITIES IN MARYLAND AND WASHINGTON, D.C.

Nuclear Regulatory Commission staff will meet with managers from the U.S. Food and Drug Administration (FDA) on Monday, December 22, to discuss concerns about radiation safety programs at FDA facilities in Laurel, Md., and Washington, D.C.

The meeting is scheduled to begin at 10:30 a.m. in the Public Meeting Room at the Region I Office in King of Prussia, Pa. Members of the public will be able to observe the meeting. NRC staff will remain afterwards to answer questions from interested members of the public.

From Aug. 20 through 22 of this year, the NRC conducted inspections at the FDA's Muirkirk Road Complex in Laurel, Md., and at its C Street site in Washington, D.C. Based on those reviews, the NRC has identified 12 apparent violations of NRC requirements, indicating problems with the radiation safety programs at those facilities. The apparent violations include: failure to calibrate instruments used for radiation surveys and to perform adequate surveys; failure to maintain records of radiation surveys; failure to survey and monitor packages for external contamination and radiation levels; failure to suspend the use of a leaking radioactive source and to report a leaking source within 30 days of identification; failure to provide annual refresher training to workers, to maintain required information in training records and to conduct a test or written assessment for training; and failure to maintain waste manifests.

The decision to hold the management meeting does not mean the NRC has determined that a violation has occurred or that enforcement action will be taken. Rather, it is being held to obtain information to enable the NRC to decide if any enforcement action is warranted. The meeting will also give the FDA an opportunity to point out any errors in the NRC's inspection report and to present any corrective actions it has implemented or plans to implement.

A copy of the inspection report is available from the Region I Office of Public Affairs and on the NRC's web site at www.nrc.gov/reading-rm/adams/web-based.html
Assistance in using the web reading room is available by calling the NRC Public Document Room at 1-800-397-4209.

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